Medinol Ltd. OCT 3 0 2000

K002130

ATTACHMENT M
SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Medinol, Ltd. is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Medinol, Ltd. choose to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the proposed **NIR™ Biliary Stent** is as follows:

Trade Name:	NIR™ Biliary Stent
Manufacturer:	Medinol Ltd., P.O.B 45026, Har-Hotzvim B, Jerusalem 91450, Israel
Device Generic Name:	Biliary Stent
Classification:	According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.
Predicate Devices:	Johnson & Johnson Palmaz Biliary Stent NIR™ Biliary Stent (K973171)

All of the devices mentioned above have been determined substantially equivalent by FDA.

Device Description:

The proposed **NIR™ Biliary Stent** is a balloon expandable stent designed to be used with a balloon dilatation catheter. The delivery catheter facilitates transhepatic access to the biliary tree and the stent is designed to maintain luminal patency of biliary strictures produced by malignant neoplasms.

Safety and Performance:

Functional and integrity bench testing and Biocompatibility testing (according to the FDA guidance document, ODE Blue Book Memorandum #G95-1, May 1, 1995, Use of International Standard ISO-10993, *"Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* were performed, and the data supported the substantial equivalence of the NIR™ Biliary Stent to the predicate devices.

Conclusion:

Based on the Indications for Use, technological characteristics and safety and performance testing, the current **NIR™ Biliary Stent** has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nasr Salman, Ph.D.
Regulatory Affairs
Medinol, Ltd.
POB 58165
Kiryat Atidim, Bldg. 3
Entrance 2, 4th Floor
Tel Aviv 61581 ISRAEL

OCT 3 0 2000

Re: K002130
NIR® Biliary Stent
Regulatory Class: II
21 CFR 876.5010/Product Code: 78 FGE
Dated: August 13, 2000
Received: August 16, 2000

Dear Dr. Salman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"
(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Bernard E. Stanland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002130

Device Name: NIR® Biliary Stent

FDA's Statement of the Indications For Use for device:

The NIR® Biliary Stent is indicated for use in the treatment of biliary strictures produced by malignant neoplasms.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002130

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)